K021924

BIONOSTICS

JUN 24 2002

*510(k) Summary**

(a) (1) **Submitter's name, address**

Bionostics, Inc.
7 Jackson Road
Devens, MA 01432

Contact Person

Kathleen Storro
Director, QA & Regulatory Affairs
(978) 772-7070 x 220

Date of preparation of this summary: 7 June 2002

(2) **Device trade or proprietary name:** **Medica EasyQC Hematocrit Control**

Device common or usual name or classification name:

Control, Hematocrit

	CLASSIFICATION		
PRODUCT NOMENCLATURE	NUMBER	CLASS	PANEL
HEMATOCRIT CONTROL	864.8625 GLK	II	HEMATOLOGY

(3) **Substantial Equivalence**

Medica EasyQC Hematocrit Control is substantially equivalent in function, safety and efficacy to currently marketed devices produced by Bionostics. In example:

Comparison of Medica EasyQC to predicate devices for substantial equivalency

Characteristic	Predicate Devices	Modified Device
Name:	RNA QC900 Hematocrit Control	Medica EasyQC Hematocrit
510(k), Date:	K955630	
Number of levels:	2	2
Analytes:	Hematocrit	Hematocrit
Container:	clear, glass ampoule	clear, glass ampoule
Fill volume:	1.7 mL	1.7 mL
Color:	clear	Clear
Matrix:	Buffered, aqueous electrolyte solution	Buffered, aqueous electrolyte solution

* This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

(4) **Description of the new device**

Medica EasyQC Hematocrit Control is a specially formulated, two-level, aqueous liquid material intended to monitor hematocrit measurement by the Medica EasyStat analyzer. **Medica EasyQC Hematocrit Control** provides a convenient method of performing periodic QC checks for laboratories selecting to measure liquid QC material as a part of their quality assurance program.

Medica EasyQC Hematocrit Control is an electrolyte solution with conductivity at two levels appropriate to simulate clinically relevant hematocrit concentrations useful to evaluate the measurement of the Medica EasyStat Analyzer.

Medica EasyQC Hematocrit Control is a non-hazardous aqueous solution containing no biological materials.

(5) **Intended use of the device**

Medica EasyQC Hematocrit Control assayed controls are intended to be used to monitor and evaluate the analytical performance of the **Medica EasyStat** for the measurement of hematocrit by conductivity.

(6) **Technological characteristics of the device.**

This material consists of buffered aqueous electrolyte solutions with conductivity to simulate clinically relevant concentrations hematocrit to span the range of values typical for such products with the same intended use.

(b) (1) **Summary of non-clinical tests submitted with the premarket notification for the device.**

Tests were conducted to verify specific performance requirements:

a) Real-time evaluation of products with the same formulation and failure mode to support stability.
b) Test precision

(b) (2) **Summary of clinical tests submitted with the premarket notification for the device.**

N/A

(b) (3) **Conclusions drawn from the clinical and non-clinical trials.**

Comparison of technological characteristics, formulation and intended use to predicate devices listed in this summary support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Kathleen Storro
Director, Quality Assurance
and Regulatory Affairs
Bionostics, Inc.
7 Jackson Road
Devens, Massachusetts 01432

JUN 2 4 2002

Re: k021924
Trade/Device Name: Medica EasyQC Hematocrit Controls
Regulation Number: 21 CFR § 864.8625
Regulation Name: Hematology QC Mixture
Regulatory Class: II
Product Code: GLK
Dated: June 7, 2002
Received: June 11, 2002

Dear Ms. Storro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number:

Device Name: Medica EasyQC Hematocrit Controls

Indications for Use:

Medica EasyQC Hematocrit Control assayed controls are intended to be used to monitor and evaluate the analytical performance of the **Medica EasyStat** for the measurement of hematocrit by conductivity.

For *In Vitro* Diagnostic Use

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K021924

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